

This is a preview of "PD ISO/TR 23021:2018". [Click here to purchase the full version from the ANSI store.](#)



BSI Standards Publication

Traditional Chinese medicine - Controlled vocabulary on Japanese Kampo crude drugs

This is a preview of "PD ISO/TR 23021:2018". [Click here to purchase the full version from the ANSI store.](#)

National foreword

This Published Document is the UK implementation of ISO/TR 23021:2018.

The UK participation in its preparation was entrusted to Technical Committee CH/100/1, Traditional Chinese Medicine.

A list of organizations represented on this committee can be obtained on request to its secretary.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

© The British Standards Institution 2018
Published by BSI Standards Limited 2018

ISBN 978 0 580 51178 3

ICS 11.120.10

Compliance with a British Standard cannot confer immunity from legal obligations.

This Published Document was published under the authority of the Standards Policy and Strategy Committee on 31 August 2018.

Amendments/corrigenda issued since publication

Date	Text affected
------	---------------

This is a preview of "PD ISO/TR 23021:2018". [Click here to purchase the full version from the ANSI store.](#)

First edition
2018-08

Traditional Chinese medicine — Controlled vocabulary on Japanese Kampo crude drugs



Reference number
ISO/TR 23021:2018(E)

© ISO 2018

This is a preview of "PD ISO/TR 23021:2018". [Click here to purchase the full version from the ANSI store.](#)



COPYRIGHT PROTECTED DOCUMENT

© ISO 2018

All rights reserved. Unless otherwise specified, or required in the context of its implementation, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Fax: +41 22 749 09 47
Email: copyright@iso.org
Website: www.iso.org

Published in Switzerland

This is a preview of "PD ISO/TR 23021:2018". [Click here to purchase the full version from the ANSI store.](#)

Contents

	Page
Foreword	iv
Introduction	v
1 Scope	1
2 Normative references	1
3 Terms and definitions	1
4 Conformance	3
5 Abbreviated terms and symbols	3
6 Preparation of terminological entries	4
6.1 Organization of preparatory work.....	4
6.1.1 Target group and subject delimitation.....	4
6.1.2 Types of referencing source.....	4
6.1.3 Evaluation of reference sources.....	4
6.2 Recording terminological data.....	4
6.2.1 Terminological entries.....	4
6.2.2 Backbone concepts.....	4
6.2.3 Administrative information.....	6
6.2.4 Physicochemical identification.....	6
6.2.5 Systematic order.....	6
7 Controlled vocabulary on Japanese Kampo crude drugs	6
7.1 General.....	6
7.2 Term list.....	7
Annex A (informative) Sample of physicochemical identification in Japanese Pharmacopoeia	44
Bibliography	46
Alphabetical Index A: Latin names of crude drugs	48
Alphabetical Index B: English names of crude drugs	51
Alphabetical Index C: Scientific names of original natural materials used for crude drugs	54

This is a preview of "PD ISO/TR 23021:2018". [Click here to purchase the full version from the ANSI store.](#)

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2. www.iso.org/directives

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received. www.iso.org/patents

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL: www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 249, *Traditional Chinese medicine*.

This is a preview of "PD ISO/TR 23021:2018". [Click here to purchase the full version from the ANSI store.](#)

Introduction

Kampo medicine is the traditional medicine of Japan. Ancient Chinese medicine was first introduced to Japan around 1 600 years ago, but Kampo medicine has developed independently from ancient Chinese medicine for the past 500 years. In the medication therapy of Kampo medicine, physicians prescribe medicinal products based on Kampo formulae that consist of various crude drugs based on Kampo medicinal theory.

The crude drugs in this document are the natural materials that are used as components of Kampo formulae in Japan. They are defined and regulated by the Japanese Pharmacopoeia and the Japanese official addendum for crude drug standards. The crude drugs used in Japan are often different from those used in China and other countries with respect to origins, part(s) of interest, and processing. In addition, there are large numbers of synonyms and homonyms among names for crude drugs.

This situation could not be ignored during the standardization of contemporary terminology for medicinal products or the latest drug information management. Rather, it is feasible that such a situation could also be considered in international standardization. However, this has yet to be achieved in ISO/TC 249.

Therefore, this document gives the terms of crude drugs used in Japanese Kampo medicine with contemporary methodologies specified in ISO deliverables and conforming to related standards on drug information management to avoid market distortion and health hazards.

Using controlled vocabulary for crude drugs with accurate expressions according to definitions of national pharmacopoeias and related documents published by national Medicines Regulatory Authorities is a fundamental step in ensuring health safety, both in medical care and in trade. The information provided by this document is expected to decrease barriers to trade.

Any formulae or traditional medicines that are not controlled by the Japanese Pharmacopoeia and related official documents published by the Medicinal Regulatory Authorities in Japan are out of the scope of this document.

This is a preview of "PD ISO/TR 23021:2018". Click here to purchase the full version from the ANSI store.

Traditional Chinese medicine — Controlled vocabulary on Japanese Kampo crude drugs

1 Scope

This document gives names for crude drugs used in Kampo formulae with concepts (or definitions) that are designated by the names to ensure safety and to facilitate international trade, including source materials and intermediate products/materials. Those names are aligned with the names for both the intermediate products and the medicinal products that are manufactured in accordance with the definitions and/or designs. This document is applicable to crude drugs “as concepts (or definitions)” used in Kampo medicine.

This document excludes the following:

- individual manufactured drug names for medicinal products “as things” derived from crude drugs;
- medicinal materials (Materia Medica) “as things”, or traditional medicines that are not regulated by the Japanese Pharmacopoeia or the related official documents published by the Medicinal Regulatory Agency, the Ministry of Health Labour and Welfare of Japan.

2 Normative references

There are no normative references in this document.

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- ISO Online browsing platform: available at <https://www.iso.org/obp>
- IEC Electropedia: available at <https://www.electropedia.org/>

3.1

natural material

naturally presenting object or substance in the real world, part of which is utilized for a medicinal purpose

Note 1 to entry: It is from plants, animals, or minerals, and usually expressed as a Latin name (scientific name).

3.2

part of interest

medicinal part

part of a *natural material* (3.1) that is utilizable for *crude drug* (3.3)

3.3

crude drug

natural medicine used as a component of a *Kampo formula* (3.6) and defined or authorized in the Japanese Pharmacopoeia^[23] and the Japanese official addendum for crude drug standards^[24]

Note 1 to entry: *Crude drug* (3.3) that was derived from a plant corresponds to HB-SNM (herbal medicament made of single natural material) in Reference [18].

Note 2 to entry: A *crude drug* (3.3) has several medicament forms, including pieces for decoction, cut crude drug, or powdered crude drug in the Japanese Pharmacopoeia.